

DG:JV
F. #2020R00308

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

- against -

ARTOM RAFAELOV,
also known as “Ariel Rafaelov,”

Defendant.

TO BE FILED UNDER SEAL

COMPLAINT AND AFFIDAVIT IN
SUPPORT OF APPLICATION FOR
ARREST WARRANT

(T. 18, U.S.C., §§ 1347, 2 and 3551 et seq.)

Case No. 22-MJ-281

EASTERN DISTRICT OF NEW YORK, SS:

I, Gabriella D. Luciano, being duly sworn, depose and state that I am a Special Agent with the Federal Bureau of Investigation (“FBI”), duly appointed according to law and acting as such.

In or about and between February 2017 and September 2021, both dates being approximate and inclusive, within the Eastern District of New York and elsewhere, the defendant ARTOM RAFAELOV, together with others, did knowingly and willfully execute and attempt to execute a scheme and artifice to defraud one or more healthcare benefit programs, as defined in Title 18, United States Code, Section 24(b), to wit: Medicare, and to obtain, by means of materially false and fraudulent pretenses, representations and promises, money and property owned by, and under the custody and control of, Medicare, in connection with the delivery and payment for healthcare benefits, items and services.

(Title 18, United States Code, Sections 1347, 2 and 3551 et seq.)

INTRODUCTION AND AGENT BACKGROUND

1. I make this affidavit in support of an application for an arrest warrant for the defendant ARTOM RAFAELOV.

2. I have been a Special Agent with the FBI since July 2019. I am currently assigned to the New York Health Care Fraud Task Force. I have personally participated in multiple investigations of fraud in billing for health care services by physicians and pharmacies. I am authorized and have received training to investigate violations of the laws of the United States, and to execute warrants under the authority of the United States. I am familiar with the records and documents maintained by health care providers and pharmacies. Through my training, education and experience, I am familiar with the techniques and methods of operation used by individuals involved in criminal health care fraud to conceal their activities and avoid detection by law enforcement.

3. I am familiar with the information contained in this affidavit based on my own personal participation in the investigation described herein, as well as my review of documents, information obtained from witnesses, and my discussions with other law enforcement personnel and witnesses. Except as explicitly set forth below, I have not distinguished in this affidavit between facts of which I have personal knowledge and facts of which I have hearsay knowledge.

4. Because this affidavit is being submitted for the limited purpose of seeking a warrant to arrest the defendant ARTOM RAFAELOV, I have not set forth each and every fact learned during the course of this investigation, but simply those facts necessary to establish probable cause to support issuance of the warrant. Except where otherwise noted, all

conversations and documents described in this affidavit are set forth in part and in substance only.

PROBABLE CAUSE

I. Background

A. The Health Care Benefit Program

5. The Medicare program (“Medicare”) was a federal health care program providing benefits to persons who were at least 65 years old or disabled. Medicare was administered by the Centers for Medicare and Medicaid Services (“CMS”), a federal agency under the United States Department of Health and Human Services (“HHS”). Individuals who received benefits under Medicare were referred to as Medicare “beneficiaries.”

6. Medicare was divided into multiple parts. Medicare Part D provided prescription drug coverage to persons who were eligible for Medicare.

7. Medicare beneficiaries obtained Part D benefits in two ways: (a) by joining a prescription drug plan, which covered only prescription drugs, or (b) by joining a Medicare Advantage Plan, which covered both prescription drugs and medical services (collectively, “Part D Plans”). Part D Plans were operated by private companies, often referred to as drug plan “sponsors,” that were approved by Medicare (“Medicare Drug Plan Sponsors”).

8. Medicare and Medicare Drug Plan Sponsors were each a “health care benefit program,” as defined by Title 18, United States Code, Section 24(b).

9. CMS assigned pharmacies a national provider identification number (“NPI”). A pharmacy dispensing medications to a beneficiary used its assigned NPI when submitting a claim for reimbursement under Medicare Part D. A pharmacy was permitted to submit claims for reimbursement under Part D only for medications that were medically

necessary and actually dispensed. A pharmacy was required to maintain records verifying that it dispensed the medications.

10. A pharmacy could participate in Medicare Part D by entering into a retail network agreement directly with Part D Plans, with one or more Pharmacy Benefit Managers (“PBMs”) or with a Pharmacy Services Administration Organization (“PSAO”). The PSAO then would contract with PBMs on behalf of the pharmacy. A PBM acted on behalf of one or more Part D Plans. Through a Part D Plan’s PBM, a pharmacy could join a Part D Plan network.

11. Typically, a beneficiary enrolled in a Part D Plan obtained prescription medications from a pharmacy authorized by the beneficiary’s Part D Plan. After filling a beneficiary’s prescription, the authorized pharmacy submitted the claim either directly to the Part D Plan or to a PBM that represented the Part D Plan.¹ The pharmacy provided, among other things, the beneficiary’s identification number, the identification number of the medical professional who ordered the prescription and the pharmacy’s identification number, such as the NPI, with the claim. The Part D Plan or the PBM determined whether the pharmacy was entitled to payment for each claim. Then, the Part D Plan or PBM, either directly or indirectly, reimbursed the pharmacy for the claim.

B. New York Law Governing the Provision of Pharmacy Services

12. The provision of pharmacy services in New York State was governed by Article 137 of the New York Education Law (“Article 137”), which regulated the profession of pharmacy, Article 33 of the New York Public Health Law (“Article 33”) and the Rules of

¹ A pharmacy could also submit reimbursement claims to a Part D Plan that was not part of the pharmacy’s network. Submission of such out-of-network claims was not common and often resulted in smaller payments to the pharmacy by the Part D Plan sponsor.

Professionalism set by the New York State Board of Regents (“Rules of Professionalism”), among others.

13. Article 137 provided, inter alia, that no person or entity was permitted to offer prescription drugs for sale unless registered as a pharmacy by the New York State Department of Education (“Department of Education”).

14. Article 137 also provided, inter alia, that no drug for which a prescription is required by the Federal Food, Drug and Cosmetic Act or by the commissioner of health shall be dispensed except upon a prescription written by a person legally authorized to issue such prescription.

C. Targretin

15. Bexarotene, brand name Targretin, was a drug used to treat skin problems arising from Cutaneous T-Cell Lymphoma. Cutaneous T-Cell Lymphoma was a rare disease, accounting for under approximately five percent of all cases of non-Hodgkin’s Lymphoma, that primarily affected the skin.

16. In or around June 2000, Targretin Gel 1% was approved as a new dosage form for Targretin by the U.S. Food and Drug Administration (the “FDA”) as a priority drug for the topical treatment of cutaneous lesions in patients with Cutaneous T-Cell Lymphoma (stage IA and IB) who had refractory or persistent disease after other therapies or who had not tolerated other therapies.

17. The use of Targretin Gel 1% was medically necessary only if other skin-directed therapies had failed or were contra-indicated for a particular patient.

18. The average wholesale price for Targretin Gel 1% was in excess of approximately \$34,000 for each 60 gram tube.

II. The Defendant and Relevant Entity

19. The defendant ARTOM RAFAELOV was a resident of Fresh Meadows, New York. RAFAELOV, together with others, owned, controlled and operated MNED, Inc., doing business as Ave M Pharmacy, located at 1206 Avenue M, Brooklyn, New York (hereinafter “Ave M”). Among other things, RAFAELOV oversaw and directed the purchasing of medications and supervised the pharmacists responsible for the submission of claims by Ave M. Ave M was registered with the New York State Office of the Professions as a pharmacy establishment.

III. The Fraudulent Scheme

20. Between approximately February 2017 and September 2021, the defendant ARTOM RAFAELOV, together with others, submitted and caused the submission of fraudulent claims for Targretin purportedly dispensed by Ave M. The Targretin that RAFAELOV and Ave M sought reimbursement for was often: (a) neither purchased nor stocked by Ave M; and (b) not medically necessary or not prescribed by the medical professionals who Avenue M claimed prescribed the Targretin.

A. Ave M Did Not Purchase or Stock Sufficient Targretin to Have Filled the Purported Claims

21. In response to a grand jury subpoena for records of any purchase of Targretin, Ave M produced records showing that Ave M purchased Targretin 1% Gel from one wholesale drug company, whose identity is known to your affiant (the “Drug Wholesaler”).

22. In addition, law enforcement issued grand jury subpoenas to four of the largest wholesale drug companies for records of the sale of Targretin to Ave M. In response, only the Drug Wholesaler produced records of the sale of Targretin to Ave M. Specifically, the

Drug Wholesaler produced invoice summaries for sales of medications, including Targretin, from the Drug Wholesaler to Ave M from February 1, 2017 through September 27, 2021.

23. The defendant ARTOM RAFAELOV signed contracts on behalf of Ave M with the Drug Wholesaler governing Ave M's purchase of all prescription and non-prescription products from the Drug Wholesaler. The defendant ARTOM RAFAELOV also signed an application for a line of credit with the Drug Wholesaler on behalf of Ave M.

24. Law enforcement also reviewed records of reimbursement claims made by Ave M to Medicare, through Part D Plans or Medicare Drug Plan Sponsors, for Targretin Gel 1% purportedly dispensed by Ave M to beneficiaries.

25. Ave M claimed to have dispensed approximately 253 60-gram tubes of Targretin Gel 1% from February 2017 to September 2021. Nonetheless, the Drug Wholesaler invoices show that Ave M purchased only 110 60-gram tubes of Targretin Gel 1% by Ave M from February 2017 through November 2021.

26. Accordingly, based on my training, experience and the investigation to date, there is probable cause to believe that, from approximately February 2017 through September 2021, Ave M did not purchase, stock or dispense many of the 60-gram tubes of Targretin 1% gel as it represented to Medicare that it did and for which it sought reimbursement from Medicare for more than \$4 million.

B. The Defendant Submitted Claims for Targretin that Were Not Medically Necessary and Were Not Prescribed by the Beneficiary's Treating Physician

27. A review of Medicare beneficiary medical records for 12 beneficiaries for which Ave M submitted claims for reimbursement for Targretin Gel 1% shows that Targretin was often not a medically necessary or reasonable treatment. In addition, a number of the

physicians who purportedly prescribed the Targretin Gel 1% did not, in fact, prescribe the medication to beneficiaries.

28. For example, Ave M submitted three claims for reimbursement for Targretin Gel 1% purportedly dispensed to Beneficiary 1, an individual whose identity is known to your affiant, from October 2018 to January 2019. Two of those prescriptions were purportedly prescriptions ordered by telephone by Doctor 1, whose identity is known to your affiant. Doctor 1, an internist specializing in cardiovascular disease, treated Beneficiary 1 from April 2018 to May 2021 for coronary artery disease, hyperlipidemia and hypertension. Doctor 1's treatment notes documented "no skin growths or lesions, no rashes" and normal skin throughout his/her treatment of Beneficiary 1. Accordingly, because Targretin Gel 1% was medically necessary only if other skin-directed therapies had failed or were contra-indicated for a particular patient, Targretin Gel 1% was not a medically necessary or reasonable treatment for Beneficiary 1.

29. In a voluntary interview, Doctor 1 told law enforcement agents that he/she did not normally prescribe Targretin. Doctor 1 stated that, if he/she had prescribed Targretin to Beneficiary 1, he/she would have had a record of prescribing Targretin in his/her patient records. Doctor 1 reviewed his/her medical records and stated that he/she had no record of prescribing Targretin to Beneficiary 1. Accordingly, there is a probable cause to believe that Ave M did not receive or fill a prescription for Targretin by Doctor 1 to Beneficiary 1, and that the prescriptions for which Ave M sought reimbursement were fraudulent.

30. As another example, Ave M submitted three claims for reimbursement for Targretin Gel 1% purportedly dispensed to Beneficiary 2, an individual whose identity is known to your affiant, from October 2017 through December 2017. Beneficiary 2 was treated by

Doctor 2, whose identity is known to your affiant. Doctor 2, a specialist in physical and rehabilitation pain medicine, treated Beneficiary 2 from July 2017 to September 2019 for cervical pain associated with diagnoses of neck pain, lumbar radiculopathy, and hypertension, diagnoses for which Targretin Gel 1% is not medically necessary. Furthermore, Doctor 2's records show no record of prescriptions for Targretin Gel 1% or any documentation of skin conditions. Accordingly, Targretin Gel 1% was not a medically necessary or reasonable treatment for Beneficiary 2.

31. In a voluntary interview, Doctor 2 told law enforcement that he/she did not know the drug Targretin off the top of his/her head, but believed it was outside of the scope of his/her specialty practice. While Doctor 2 could not recall Beneficiary 2's first name, he/she told law enforcement agents that he/she had not prescribed a cream for her patient. There was no record of Doctor 2 prescribing Targretin to Beneficiary 2 in Doctor 2's medical records. Accordingly, there is probable cause to believe that Ave M did not receive or fill a prescription for Targretin by Doctor 2 to Beneficiary 2, and that the prescription for which Ave M sought reimbursement was fraudulent.

32. The review of Medicare beneficiary medical records showed additional examples of claims for reimbursements where Targretin Gel 1% was not a medically necessary or reasonable treatment. For example, Ave M submitted 10 claims for reimbursement for Targretin Gel 1% purportedly dispensed to Beneficiary 3, an individual whose identity is known to your affiant, from February 2018 to December 2018. Beneficiary 3 was an elderly patient treated for osteoarthritis, gastroesophageal reflux disease, osteoporosis, insomnia, incontinence and Alzheimer's related dementia. While the treating physician treated the beneficiary with topical creams for multiple rashes, the office visit notes do not mention prescribing Targretin Gel

1%. In addition, there was no documentation of cancer or any notes of skin cancer evaluation or testing. Accordingly, Targretin Gel 1% was not a medically necessary or reasonable treatment for Beneficiary 3.

33. As another example, Ave M submitted 16 claims for reimbursement for Targretin Gel 1% purportedly dispensed to Beneficiary 4, an individual whose identity is known to your affiant, from October 2018 through January 2020. Beneficiary 4 was treated by a physician who specialized in Internal Medicine for diagnoses of gout, gastroesophageal reflux disease, coronary artery disease, hypertension and chronic obstructive pulmonary disease. Each of the doctor's medical notes documented "skin: no lesions noted." Targretin Gel 1% did not appear on any medication lists, and there was no record of any skin testing relevant to any medically indicated condition associated with Targretin Gel 1%. Accordingly, Targretin Gel 1% was not a medically necessary or reasonable treatment for Beneficiary 4.

C. Ave M Fraudulently Received Payment from Medicare

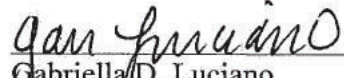
34. The defendant ARTOM RAFAELOV, together with others, submitted and caused Ave M to submit approximately 253 claims for Targretin Gel 1% to Medicare, including claims that were medically unnecessary and not ordered by a medical professional, as represented in the submitted claims, or were never provided to the beneficiary by Ave M. As a result, Medicare reimbursed Ave M approximately \$30,000 for each tube of Targretin Gel 1% it claimed to have dispensed, for a total of approximately \$7,539,770.22.

35. As a result of the fraudulent scheme, a health care benefit program, to wit: Medicare, has paid millions of dollars in reimbursements for fraudulent claims.

CONCLUSION


36. Wherefore, your affiant respectfully requests that an arrest warrant be issued for the defendant ARTOM RAFAELOV so that he may be dealt with according to law.

37. Because public filing of this document could result in a risk of flight by the defendant ARTOM RAFAELOV, who has not yet been apprehended, as well as jeopardize the government's investigation, your affiant respectfully requests that this affidavit and the arrest warrant be filed under seal until further order of the Court, except that law enforcement officers may disclose this affidavit as necessary to effectuate the arrest and arraignment of the defendants.



Gabriella D. Luciano
Special Agent
Federal Bureau of Investigation

Sworn to before me via telephone on this
14th day of March, 2022



THE HONORABLE JAMES CHO
UNITED STATES MAGISTRATE JUDGE
EASTERN DISTRICT OF NEW YORK